

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON**

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327 JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
THIS DOCUMENT RELATES TO: WAVE 3 CASES LISTED IN EXHIBIT A TO DEFENDANTS' MOTION	

**REPLY MEMORANDUM IN SUPPORT OF MOTION TO EXCLUDE
GENERAL-CAUSATION OPINION TESTIMONY OF KONSTANTIN
WALMSLEY, M.D.**

This Court's Pretrial Order #239 limited “[e]ach side . . . [to] one response and one reply in the main MDL to each *Daubert* motion.” 10/5/16 First Amended Docket Control Order #239(B)(2). Yet Plaintiffs Baker, Phillips, and Ward filed one response (*see* Pls.' Opp'n (Dkt. 2941)) and Plaintiffs Berry, Booher, Mattingly, and Ludwig filed a separate response (*see* Pls.' Opp'n (Dkt. 2953)). These multiple filings are contrary to this Court's order and should not be permitted or condoned. Despite Plaintiffs' duplicative effort, they fail to give any valid reasons why this Court should depart from its Wave 1 ruling excluding Dr. Walmsley's IFU opinions because he does not possess the “additional expertise” necessary to opine about what should be included in an IFU. *See In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4961675, at *3 (S.D.W. Va. Aug. 25, 2016). Nor do they show how General Opinion No. 2—to the extent it sets forth a safer-alternative-procedures opinion—is relevant to any claim or issue in these cases.

ARGUMENTS AND AUTHORITIES

I. Dr. Walmsley's IFU opinions should be excluded for the same reason they were in Wave 1: he is not qualified to opine about what should be included in an IFU.

Dr. Walmsley's IFU opinions set forth in General Opinion Nos. 1 and 2 in these Wave 3 cases are essentially identical to those opinions offered by him in Wave 1 that this Court excluded because he "does not possess the additional expertise to offer expert testimony about what an IFU should or should not include." *In re: Ethicon Inc.*, 2016 WL 4961675, at *3. As the Court noted in its order, Dr. Walmsley's opinions focus on "whether the relevant IFU should have included warnings about particular complications." *Id.*; Defs.' Mem. (Dkt. 2824) at 2-3. In their multiple oppositions, Plaintiffs fail to mention the Court's Wave 1 Order, let alone address why the same result should not occur here. Instead, Plaintiffs cite to case law from this Court and elsewhere that precedes the Wave 1 Order, and does not involve Dr. Walmsley and the opinions that he offers both here and in Wave 1. *See* Pls.' Opp'n (Dkt. 2941) at 3-4; Pls.' Opp'n (Dkt. 2953) at 3-4.

Nor do Plaintiffs make any attempt to establish that Dr. Walmsley's factual circumstances have changed. They do not contend that Dr. Walmsley has since obtained the additional expertise necessary to offer his IFU opinions in the two months since this Court issued its Wave 1 Order.¹ Because Dr. Walmsley does not possess the required expertise to opine about what should be included in an IFU, his opinions set forth in General Opinion Nos. 1 and 2 should be excluded just as they were in Wave 1.

¹ In fact, in a deposition recently taken in *Mattingly*, Civil Action No. 2:12-cv-03097, Dr. Walmsley confirmed once again that he has never written or been asked to write an IFU for a medical device, and has never consulted with a medical device manufacturer about what should or should not be included in an IFU. *See* Ex. A, Walmsley 10/12/16 Rough Dep Tr. (*Mattingly*) 25:13-16, 25:22-25.

II. Whether alternative surgical *procedures* are available has no bearing on claims for design defect, or on any other topics asserted by Plaintiffs.

Ethicon challenged Dr. Walmsley's alternative-procedures opinion on relevancy grounds, yet some Plaintiffs respond with a nonresponsive qualifications argument. *See* Pls.' Opp'n (Dkt. 2941) at 5. Even so, Plaintiffs have not shown how Dr. Walmsley's opinion that safer alternative surgical *procedures* exist is relevant to any of these in cases in which Plaintiffs are required to prove the availability of a safer alternative *design* to prove their design-defect claims.

Plaintiffs' attempts to otherwise establish relevance fall flat. Plaintiffs' risk-benefit argument (*Id.* at 5-6; Pls.' Opp'n (Dkt. 2953) at 6) should be rejected because a risk-benefit analysis is part of the analysis for design defect, which, as shown, rests on the existence of an alternative design, and an alternative surgical *procedure* is not an alternative *design* that would support a claim for design defect. *See* Defs.' Mem. (Dkt. 2824) at 4-5. Further, Plaintiffs cite to no legal authority to support their argument that Dr. Walmsley's alternative-procedures opinion is relevant to show "Ethicon's reasonableness in putting these devices on the market" or to support a claim for punitive damages. Pls.' Opp'n (Dkt. 2941) at 5-6; Pls.' Opp'n (Dkt. 2953) at 6.

In fact, Plaintiffs' oppositions make clear they intend to offer Dr. Walmsley's alternative-procedures opinions for at least two improper purposes. First, this opinion ultimately challenges the decision of Plaintiffs' surgeons to implant Ethicon's mesh devices rather than use one of the alternative surgical procedures identified by Dr. Walmsley. *See* Defs.' Mem. (Dkt. 2824) at 4. Thus, Plaintiffs are asking this Court allow the jury to find Ethicon liable essentially because Dr. Walmsley would have selected a different surgical procedure for Plaintiffs. They cite to no authority permitting a physician's choice in surgical procedure to lead to manufacturer liability

for a defective product, and therefore, the use of Dr. Walmsley's alternative-procedures opinion for this purpose should not be permitted.

Second, Plaintiffs would use Dr. Walmsley's alternative-procedures opinion to lead the jury to find it "less reasonable" that Ethicon ever marketed the TVT products at all. *See* Pls.' Opp'n (Dkt. 2941) at 5-6 (making repeated references to the issue of the reasonableness of Ethicon's decision to market, and to continue marketing, the TVT products); *see also* Pls.' Opp'n (Dkt. 2953) at 6. But again, Plaintiffs point to no legal authority that permits manufacturer liability for merely marketing a product. There is none. *See, e.g., Jones v. Amazing Prods., Inc.*, 231 F. Supp. 2d 1228, 1250 n.25 (N.D. Ga. 2002) (declining to recognize a claim that the product should not have been marketed, noting that "perhaps the best place for a determination whether a product should be banned is a legislative or regulatory body, not a court").

Plaintiffs have shown that they intend to use Dr. Walmsley's alternative-procedures opinion for improper purposes. They should not be permitted to do so.

CONCLUSION

Ethicon asks this Court to grant its Motion to Exclude the General-Causation Testimony of Konstantin Walmsley, M.D., and limit his opinions for the reasons stated above and in its memorandum in support of its Motion.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on October 20, 2016, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

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